ORIGINAL

BEFORE THE
DEPARTMENT OF TRANSPORTATION

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Federal Aviation Administration In the Matter of: Antidrug And Alcohol Misuse Prevention Programs For Personnel Engaged In Specified Aviation Activities Notice No. 00-14	Docket No. FAA-2000-8431-4
Coast Guard In the Matter of: Chemical Testing	Docket No. USCG-2000-7759 - 5
Research and Special Programs Administration In the Matter of: Drug And Alcohol Testing For Pipeline Facility Employees Notice No. 1	Docket No. RSPA-00-8417 - 4
Federal Railroad Administration In the Matter of: Control Of Alcohol And Drug Use: Proposed Changes To Conform With New DOT Transportation Workplace Testing Procedures Notice No. 48	Docket No. FRA-00-8583-2

Federal Motor Carrier Safety Administration In the Matter of: Controlled Substances And Alcohol Use And Testing	Docket No. FMCSA-2000-8456 - 12

Federal Transit Administration In the Matter of: Prevention Of Alcohol Misuse and Prohibited Drug Use in Transit Operations	Docket No. FTA-2000-8513 - 37

COMMENTS OF THE AIR LINE PILOTS ASSOCIATION AND TRANSPORTATION TRADES DEPARTMENT, AFL-CIO

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THE AIR LINE PILOTS ASSOCIATION AND
THE TRANSPORTATION TRADES DEPARTMENT
OF THE AFL-CIO

Introduction and Summary

The Air Line Pilots Association ("ALPA") is the principal labor union representing the nation's commercial pilots. It represents more than 66,000 pilots at 47 airlines in the United States and Canada. The Transportation Trades Department of the AFL-CIO ("TTD") is an organization of the AFL-CIO comprised of 33 unions that represent employees in the transportation industries.[1] ALPA submits these comments on its own behalf and on behalf of TTD in response to the above-captioned Notice of Proposed Rulemaking ("NPRM").

ALPA and TTD maintain their opposition to mandatory "validity" testing in the manner in which DOT is seeking to implement it. We remain concerned that validity testing lacks fundamental safeguards, fails to meet acceptable scientific standards and continues to present an unacceptable risk to innocent employees.

Recent history has shown that innocent workers have been falsely reported to have adulterated or substituted their urine samples, and have been terminated from their jobs as a result. The severe consequences to an individual accused of tampering with his or her specimen demands that any such testing be in accordance with the highest standards of forensic science and due process.

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[1] The unions represented by TTD are listed in the attachment to these Comments.

While we appreciate that DOT incorporated some of our suggestions in the final version of Part 40, many of our basic concerns remain unresolved. We refer the Department to ALPA's Comments submitted in response to the NPRM on Part 40 (Notice OST-99-6578) and incorporate by reference the concerns stated therein. (See Attachment).

As we emphasized in our prior Comments and as has been born out by ALPA's experience after the close of the Part 40 NPRM comment period, if validity testing in accordance with the rules now in effect under Part 40 is going to be required, it is absolutely essential that employees and labor unions have access to information in the possession of employers, service agents and laboratories that can reveal laboratory and other testing, analytic and reporting errors. It is similarly vital that employees and labor unions have the right to a forum within which to present and have considered such exculpatory evidence. We strongly object to the proposed deletion of the access to information provisions in the drug and alcohol testing regulations of the FAA and other transportation sector agencies. Nor do we consider the release of information provisions in Part 40 sufficient to adequately protect employees. In our view, the failure to provide employees access to such relevant information denies them due process.

Finally, we recognize and appreciate the revisions and clarifications in FAA's drug and alcohol testing regulations that have been proposed to make them consistent with the prior changes to the airmen medical certification regulations and standards in 14 C.F.R. Part 67.

I. EMPLOYEES' REGULATORY RIGHTS TO OBTAIN INFORMATION SHOULD BE ENHANCED NOT DIMINISHED.

A. The Provisions In The Drug And Alcohol Testing Regulations Setting Forth Employers' Obligations To Provide Employees With Relevant Information Should Not Be Deleted.

Currently both drug and alcohol testing regulations have provisions that entitle employees to obtain, and require employers to provide, records relevant to charges that an employee violated the anti-drug and alcohol misuse provisions. For example, with respect to alcohol misuse, "[a] covered employee is entitled, upon written request, to obtain copies of any records pertaining to the employee's use of alcohol, including any records pertaining to his or her alcohol tests." 14 C.F.R. Appendix J to Part 121, IV.C.2. A similar provision exists in the drug testing regulations obligating an employer to release "information regarding an employee's drug testing results, evaluation, or rehabilitation" upon an employee's written request. 14 C.F.R. Appendix I to Part 121, VI.D.

The NPRM proposes to delete each of these provisions, stating that access to information is provided for under the revised Part 40. However, Part 40 does not contain similar language and is, in itself, far too limited in the information it requires to be released.

The current regulatory language that the NPRM proposes to eliminate requires a broad release of information relating to drug and alcohol use, evaluations or rehabilitation, as well as information pertaining to test results. This broad language has been valuable in providing a right of access to relevant information for

employees. The language in revised Part 40 (Section 40.331) is not the same and could likely lead to disputes over the breadth of its reach. It is essential that the regulations continue to protect employees' right of access to such information.

The current regulatory language also places the burden on employers to provide such information. This is as it should be, and should remain. While we agree that MROs, laboratories and other service agents should be directly responsible under the regulations to provide information to employees, and subject to DOT sanction (or the Public Interest Exclusion) if they fail to comply with their regulatory obligations, employers should also remain responsible and accountable for ensuring that the MRO, laboratory or other contracting service agent properly fulfills its obligations under the regulations. The contractual relationship the employer has with both the MRO and the laboratory gives the employer leverage in securing timely compliance with disclosure provisions. Eliminating the employer's responsibility invites a prolonged battle for access to information between the worker and the MRO, laboratory, and other service agents. The regulatory language should be clear that the employer remains ultimately responsible for ensuring that employees are provided with such information.

B. Laboratories And Other Service Agents Should Be Required To Produce Extensive Information To Affected Employees To Afford The Opportunity to Identify Gross Laboratory Errors.

In the prefatory section to the issuance of the revisions to Part 40, DOT describes a "significant series of errors by one laboratory involved in validity testing" that it learned of in September 2000. 65 Fed. Reg. 79481 (Dec. 19, 2000). DOT

describes some of the problems and reports that (a) caused the employer in that case to terminate its contract with that laboratory and re-hire five employees whose test results had been thrown into question by the laboratory's errors; (b) caused the laboratory director to resign; (c) caused DOT to refer issues of possible evidence tampering by the laboratory to the DOT and HHS Inspector Generals for further investigation; and (d) caused HHS to embark on a special laboratory investigation which identified further errors resulting in the cancellation of over 300 test results. Id. at 79481-2.

As DOT is aware, ALPA handled the case that uncovered these laboratory problems. It involved a Delta Air Lines pilot with 20 years of service, a previously unblemished record and no prior evidence of any drug or alcohol problems, who steadfastly maintained his innocence of any wrongdoing, but who was fired and had his pilot's certificate emergency revoked based solely on the levels of creatinine and specific gravity reported to be in his urine by LabOne. In the same time frame that this pilot was fired, several flight attendants at the same airline were also terminated for allegedly "substituting" their urine samples, also based solely on reports by LabOne.

What is significant about the pilot's case for purposes of these Comments is that the serious laboratory problems uncovered – those pertaining to the handling and analysis of the individual's sample, as well as those reflecting longstanding and widespread laboratory practices affecting many other employees' tests – were not apparent from the Custody and Control Form ("CCF") nor the "litigation" or "data

package." For this reason, it is essential that the regulations make clear that employers, laboratories and other service agents are not limited to producing only the CCF and litigation or data package to employees.

In the pilot's case, it was only by obtaining additional and extensive documents and testimonial evidence through formal discovery that the problems were revealed. It is also noteworthy that the pilot's case settled after glaring laboratory misconduct came to light prior to trial, and therefore before ALPA had the opportunity to put on other extensive evidence it had gathered from voluminous laboratory documents and NLCP inspection reports, which revealed numerous, equally significant, laboratory problems.[2]

Because the pilot was a certificated employee, and because the FAA revoked his license at that time, he was entitled to the NTSB appeal procedures, including discovery, judicially ordered subpoenas, and a hearing before an administrative law judge. The ability to use these procedures and gain access to extensive laboratory documents and have them analyzed by an outside expert was outcome determinative. Without access to such information, an employee would not be able to identify significant laboratory problems of the type encountered in that case.

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[2] Although the pilot was reinstated with full backpay and benefits restored and his record cleared by his employer and the FAA, he is still harmed by the bias of some individuals who lack full knowledge of the extensive laboratory problems uncovered which were never put into evidence in any hearing. His case and that of the flight attendants at the same airline illustrates the extreme difficulty in getting reviewing officials to consider that numbers "officially" reported by a laboratory can be inaccurate and unreliable. Even in a case where gross laboratory misconduct is observed and extensive procedural errors found, overcoming that stigma can be an enormous undertaking.

It is useful to examine some of the specific information and the means by which it was obtained that led to the detection of the LabOne problems. In that case, among other things, ALPA obtained the lab's Standard Operating Procedures ("SOP") used for testing creatinine and specific gravity; instrument maintenance and corrective actions documents; all quality control data for the testing of specific gravity and creatinine during the month before and the month after the pilot's urine was tested; and National Laboratory Certification Program ("NLCP") inspection reports and critiques for the relevant period. All of this information was essential in order to identify various problems with the laboratory.

For example, the finding that a reading of "LLL" on the instrument reading specific gravity is an error message was not self evident from the litigation package nor did the laboratory personnel readily acknowledge it. Only by having access to, and obtaining, the SOP and the manufacturer's handbook for the instrument used to measure specific gravity was that crucial fact obtained.

It is also necessary to gain access to information to understand the cause or significance of an unusual reading or error message. Our experience shows that an error that might seem insignificant can indicate a far more serious problem when interpreted in conjunction with other facts and data.

In the pilot's case, information about the laboratory's calibration procedures, in conjunction with the "LLL" error message, the absence of a low specific gravity control, and the NLCP proficiency data, led an outside expert to conclude that the specific gravity instrument appeared to be under-reporting specific gravity levels

during the applicable time period. Certain evidence about the manner in which laboratory personnel calibrated the specific gravity instruments raised questions about the nature of the water used to zero the specific gravity instrument. Using less than pure or less than fully deionized water to zero the instrument (set the meter to 1.000), would cause subsequent samples to read below 1.000. This error would be revealed by a low control or by an error message from the instrument.

At the time of the pilot's test, the laboratory failed to run a low control for specific gravity, and failed to take any corrective action in response to the instrument's error message generated when the pilot's specimen was tested. The NLCP external proficiency report for the applicable time period also reported a value for the low specific gravity proficiency test sample that was two standard deviations below the group mean. There was no documentation of review or of corrective action by the laboratory in response to that low value on the NLCP proficiency report.

Evidence such as this is highly probative as to whether reported test results are scientifically supportable. It is essential for employees and labor unions to have access to such information in order to protect innocent employees as well as the integrity of the testing system itself. It is also in the broader public interest to uncover a laboratory's errors and prevent faulty test results. ALPA's discovery of the LabOne problems in the pilot's case led to further investigation by HHS that uncovered additional problems at other laboratories meriting the cancellation of over 300 tests of other affected employees.

Quality control data is also pivotal evidence. Poor quality control can make testing procedures during a particular time frame scientifically unreliable and inaccurate. For example, the review of such data in the pilot's case revealed several significant problems. First, it showed that the lab was not using a required low creatinine control of less than 5.0 mg/dl (required by federal guidance, PD 37). Instead, for its "low" creatinine control, it used a control of 40 mg/dl and allowed a tolerance of error of $\pm$20% when testing its equipment with that control. That meant that if the 40 mg/dl control was tested and reported a result of 32 mg/dl, the laboratory considered it satisfactory. It also meant that if the controls were reporting results with such variance, so too could the actual results reported on employees' tests. Thus an employee whose creatinine level was actually "dilute" might have a lab reported result of "substituted."

Second, the quality control data showed that the actual performance of the creatinine controls had significantly deteriorated approximately two weeks before the pilot's specimen was tested. Records for both the high and low creatinine controls showed that in the weeks before the pilot's sample was tested, and in the days following it, both the low control and the high control showed multiple indicators of increased imprecision and reduced accuracy on the particular instrument used to test this pilot's urine sample. In the creatinine assay, repeated measurements on known quality control samples on the instrument used for the pilot's specimen revealed a day to day spread of 12 to 16 mg/dl at both low and high control levels, which was double the values obtained before and after this period (a

spread of 8-9 mg/dl at the low control of 40 mg/dl, and a spread of 7-9 mg/dl at the high control of 73 mg/dl before and after this period). Such data indicate deterioration in the performance of the instrument on which the quality control specimens were tested, which in the pilot's case, was the same machine on which his test results were based. Under such circumstances, a reading of 0 creatinine could correspond to a true value of greater than 5 mg/dl.

Additionally, the evidence showed no SAMHSA designated official person was responsible for the quality assurance of creatinine or specific gravity testing. The laboratory's Quality Control coordinator was unqualified to, and did not, supervise or analyze quality control data for trends, bias, scatter, or acceptability by scientifically recognized criteria such as the Westgaard Rules. The NLCP inspection reports also showed that the laboratory had been repeatedly cited for quality control deficiencies by the SAMHSA NLCP inspectors.

Significantly, these data caused an outside expert to conclude that the precision and accuracy problems in the creatinine and specific gravity assays at LabOne in the applicable time period, as evidenced by the quality control records, would not have allowed a precise or accurate determination as to whether the specimens tested were below the substitution cut-offs (less than 5 mg/dl creatinine and less than 1.001 specific gravity) or merely dilute (less than 20 mg/dl creatinine and less than 1.003 specific gravity).

While there were many other laboratory errors identified from the documents obtained and the deposition testimony taken in the pilot's case, the above examples

suffice to demonstrate how essential such data are to determining whether reported test results are truly accurate and reliable and justify ending a person's career and livelihood. In the pilot's case, glaring laboratory misconduct was also revealed which, in and of itself as DOT recognized, "undermined the credibility of the laboratory" and resulted in a settlement of the case. (65 Fed Reg. 79481). But even the egregious conduct (which included document manipulation -- signature copying and backdating; high level laboratory personnel misrepresenting academic qualifications and then lying about them under oath; even an apparent attempt to destroy evidence) were not discernable from the litigation packet or the custody and control form. These were uncovered only after careful review of records and through deposition cross examination.

In sum, as ALPA's experience has shown, access to all relevant documentation is absolutely necessary to identify serious laboratory errors and faulty procedures. Such relevant evidence includes but is not limited to: laboratory quality control records, laboratory performance records on proficiency testing, results of laboratory inspections and critiques, all laboratory internal and external quality control data, instrument maintenance and corrective action documentation; instrument and software instruction manuals, as well as laboratory Standard Operating Procedures. Access to such information should be readily available for all employees subject to testing under the DOT regulations, and should not depend upon whether a particular individual has access to additional administrative or judicial procedures because he or she becomes subject to certificate action.

The pilot's access to information in the above case was in stark contrast to that of the terminated flight attendants at the same airline. Those individuals are non-certificated employees, not represented by a labor union, and had no clear avenue of recourse or ready access to discovery. Had evidence of the laboratory's serious deficiencies not been discovered in the pilot's case, the flight attendants may well have permanently lost their careers. Likewise a pilot not subject to certificate action and not covered by a collective bargaining agreement, or another type of uncertificated employee, who is fired based on a reported test result may have no due process rights, and can be similarly deprived of access to the very information necessary to exculpate him. For these reasons, we urge DOT to ensure that the regulations make clear that all employees have the right to obtain the type of information discussed above.

Moreover, oversight of the testing process by interested parties and affected employees is one of the best means of protecting and ensuring the integrity of the testing process. Since unions represent affected employees, they too should have the right under the regulations to receive the types of summary information and trend data made available to employers, MROs and DOT.

Finally, information about certified laboratories' procedures for testing employees under DOT-mandated tests, and any problems uncovered in the course of them, should be publicly available. We are extremely concerned about the DOT's resistance thus far to disclosing information about the over 300 cancelled tests. We are similarly disturbed about recent efforts by certified laboratories to limit access or disclosure of such

information by requesting or attempting to insist on confidentiality agreements or protective orders. As a matter of public policy, such information should be publicly accessible to aid employees in identifying faulty testing procedures that may have caused the reporting of erroneous test results. DOT's greater interest should be in safeguarding the integrity of the testing program – not in protecting pecuniary interests of certain laboratories. The regulations should state that access to such information is required and that any attempts to shield such disclosure is not permissible.

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Dated: June 14, 2001

TTD AFFILIATES

The following labor organizations are members of and represented by the TTD:

Air Line Pilots Association
Amalgamated Transit Union
American Federation of State, County and Municipal Employees
American Federation of Teachers
Association of Flight Attendants
American Train Dispatchers Department
Brotherhood of Locomotive Engineers
Brotherhood of Maintenance of Way Employes
Brotherhood of Railroad Signalmen
Communications Workers of America
Hotel Employees and Restaurant Employees Union
International Association of Fire Fighters
International Association of Machinists and Aerospace Workers
International Brotherhood of Boilermakers, Blacksmiths, Forgers and Helpers
International Brotherhood of Electrical Workers
International Brotherhood of Teamsters
International Longshoremen's Association
International Longshoremen's and Warehousemen's Union
International Organization of Masters, Mates & Pilots, ILA
International Union of Operating Engineers
Marine Engineers Beneficial Association
National Air Traffic Controllers Association
National Association of Letter Carriers
National Federation of Public and Private Employees
Office and Professional Employees International Union
Professional Airways Systems Specialists
Retail, Wholesale and Department Store Union
Service Employees International Union
Sheet Metal Workers International Association
Transportation • Communications International Union
Transport Workers Union of America
United Mine Workers of America
United Steelworkers of America

March 2001

ATTACHMENT